UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,622	11/18/2003	Xian-Ping Lu	4865-105 US	4873

7590 10/25/2006

Patrick H. Higgins
997 Lenox Drive
Building 3
Lawrenceville, NJ 08648

EXAMINER	
COLEMAN, BRENDA LIBBY	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,622	LU ET AL.	
	Examiner	Art Unit	
	Brenda L. Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12,14,16,17,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-7,12,14,16,20 and 21* is/are allowed.

6)☒ Claim(s) *8,9 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9, 12, 16, 16, 17, 20 and 21 are pending in the application.

This action is in response to applicants' amendment dated August 7, 2006. Claims 1-8, 12, 14, 16, 17 and 20 have been amended and claims 10, 11, 13, 15, 18, 19 and 22-28 have been canceled.

Response to Arguments

Applicant's arguments filed August 7, 2006 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 10-19 of the last office action labeled paragraph 4, the applicant's arguments have been fully considered, however they were not found persuasive. The applicant's stated that claims 10-11, 13, 15 and 18-19 have been canceled and claim 17 has been amended. Claim 17 is such that it is to a method of treatment of a condition mediated by Peroxisome Proliferator-Activated Receptors (PPAR) comprising administering to a subject in need thereof an effective amount of a compound according to claim 1.

While being enabling for dyslipidemia, hypertension and type 2 diabetes, does not reasonably provide enablement for all disorders claimed herein. Wilson et al., provided by the applicant states that PPARγ agonists have been successfully employed in the treatment of hypertriglyceridemia or type 2 diabetes in humans. Wilson also states that PPARγ agonists **may have therapeutic potential** in the treatment of inflammatory bowel disease and that further studies are necessary to explore the potential of PPARγ agonists in the treatment of inflammation and artheroscelerosis. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The scope of the method claims are not adequately enabled solely based on its inhibitory effect of PPARγ provided in the specification. The scope of "cardiovascular disease" cannot be deemed enabled. The notion that a compound could be effective against cardiovascular disease in general is contrary to our current understanding of how pharmacologicals work. All attempts to find a pharmaceutical to treat cardiovascular disease generally have thus failed. According to MPEP §2106.02, "it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979)."

In evaluating the enablement question, several factors are to be considered. In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See *In re Ruskin*, 148 USPQ 221; *Ex parte Jovanovics*, 211 USPQ 907; MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. *Genentech Inc. v. Novo Nordisk* 42 USPQ2d 1001.

Claim 17 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for dyslipidemia, hypertension and type 2 diabetes, does not reasonably provide enablement for all disorders claimed herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for reasons of record and stated above.

2. The applicants amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraphs 5a), b), c), d), e), f), g), i), k) and l) of the last office action, which is hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections of claim 8, 9 and 17 labeled paragraphs 2h) and 2j) of the last office action, the applicant's arguments have been fully considered, however they were not found persuasive.

h) The applicants' state that the amended claims in association with the remarks otherwise presented herewith to address the issues raised by the

Examiner. However, claims 8 and 9 have not been amended with respect to "non" in the definition of Ar^2.

Claims 8 and 9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention, for reasons of record and stated above.

j) The applicants' stated that the amended claims in association with the remarks otherwise presented herewith to address the issues raised by the Examiner. The rejection of claim 17 was on the grounds that it is indefinite, in that it is not known which diseases are capable of being responsive to PPAR activity. The scope of diseases and/or disorders associated with the activity of PPAR could alter over time. The applicants' are not entitled to preempt the efforts of others. Claim 17 has been amended such that the claim is directed to a method of treatment of a condition mediated by Peroxisome Proliferator-Activated Receptors (PPAR), thus the applicants have not set forth the metes and bounds of these claims.

Claim 17 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention, for reasons of record and stated above.

3. The applicants amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 6) of the last office action, which is hereby **withdrawn**.

4. The applicants amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection labeled paragraph 7) of the last office action, which is hereby **withdrawn**.

Claim Objections

5. Claim 8 is objected to because of the following informalities: it is not known what is meant by the period at the end of step c) indicating the end of the claim, which is not so. Appropriate correction is required.

Allowable Subject Matter

6. Claims 1-7, 12, 14, 16, 20 and 21 are allowed. None of the prior art of record or a search in the pertinent art area teaches the compounds, compositions and method of use of the compounds of formula (I) as claimed herein.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brenda Coleman

Brenda L. Coleman
Primary Examiner Art Unit 1624
October 20, 2006